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09/924,320

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Mark Huang

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EXAMINER

ARAJ, MICHAEL J

ART UNIT

PAPER NUMBER

3775

NOTIFICATION DATE

DELIVERY MODE

12/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/924,320 | Applicant(s) HUANG, MARK | |
| | Examiner MICHAEL J. ARAJ | Art Unit 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 22-26,28,29 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-21 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2007 has been entered.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 2 and 4 do not have lines, numbers and letters that are uniformly thick, well defined, clean and durable. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-10, 12, 14, 17-21 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (US Patent Number 6,066,156), cited by applicant on 1449, paper number 102802

Yan discloses an apparatus for treating a vascular condition comprising a balloon including an outer first layer, e.g. 16, and an inner second layer, e.g. 14, the

outer first layer covering only a limited portion of the inner second layer; and a stent, e.g. 18, disposed on the outer first layer of the balloon, wherein the outer first layer flows into gaps, e.g. 15, formed in the stent when the apparatus is heated to a predetermined temperature, and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps (see figures 1 and 3, column 5, lines 64-66, column 7, lines 65-67 and column 8, lines 1-7), wherein the outer layer and the inner layer comprise a co-extruded laminate (see column 7, lines 23-28), wherein the outer layer comprises a tie layer material (see column 7, lines 23-28), wherein the outer layer comprises a functionalized material (see column 7, lines 14-17 and 23-28). In addition, Yan teaches that the functionalized material comprises at least one material selected from a group consisting of: polyethylene, ethylene-vinyl-acetate, acrylate, Bynel®, and Plexar® (see column 7, lines 14-17), wherein the functionalized material is not tacky at temperatures below the predetermined temperature (see column 7, lines 31-34). The stent covers at least 55 percent, at least 70 percent, and at least 90 percent of the outer layer (see figures 1 and 3).

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Yan, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 11, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (US Patent Number 6,066,156).

Yan discloses the claimed invention except the predetermined temperature comprising a temperatures range of about 50 to 70 degrees Celsius, the balloon providing at least 200 gram force of a stent retention force, .the balloon providing at least 300 gram force of a stent retention force, or the balloon providing at least 90 gram force of a stent retention force. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Yan with the predetermined temperature comprising a temperatures range of about 50 to 70 degrees Celsius, the balloon providing at least 200 gram force of a stent retention force, .the balloon providing at least 300 gram force of a stent retention force, or the balloon providing at least 90 gram force of a stent retention force, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed August, 30 2007 have been fully considered, but they are not persuasive. Examiner respectfully disagrees with applicant regarding the Yan reference. It is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Based on what is being claimed in claim 1, Yan discloses a balloon including an outer first layer, e.g. 16, and an inner second layer, e.g. 14, the outer first layer covering only a limited portion of the inner second layer; and a stent, e.g. 18, disposed on the outer first layer of the balloon, wherein the outer first layer, e.g. 16, flows into gaps, e.g. 15, formed in the stent when the apparatus is heated to a predetermined temperature (see figure 3 and column 7, lines 1-3). This is clearly seen in figure 3. Furthermore, the adhesive that is already on the balloon flows into gaps formed in the stent (see figure 3 and column 7, lines 1-3). Moreover, Yan discloses that the balloon can be coated with adhesive prior to heating (see column 4, lines 3-11). Regarding claim 9, Yan discloses wherein when the balloon is heated at a predetermined temperature the outer layer, e.g. 16, flows into gaps, e.g. 15, formed in the stent, e.g. 18, while the inner layer, e.g. 14,

does not flow (see figure 3). Furthermore, Yan can provide a non-tacky outer layer (see column 7, lines 31-34).

Applicant also argues that the “general conditions” of the claims are not met by Yan because the embodiment of Figure 1 loses its tackiness at temperatures above 38 degrees Celsius. The specific conditions necessary that were not met in claims 2, 11, 13, 15 and 16 were appropriately addressed in the 103 rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Araj/
Examiner, Art Unit 3775
/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733